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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,962	11/13/2006	Richard Joseph Fagan	C&R-106	6818

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EXAMINER	
KIM, ALEXANDER D	
ART UNIT	**PAPER NUMBER**
1656	

MAIL DATE	DELIVERY MODE
11/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,962	FAGAN ET AL.	
	Examiner	Art Unit	
	Alexander D. Kim	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *46-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *46-64* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. By virtue of a preliminary amendment filed on 06/17/2005, claims 1-45 have been canceled; and new claims 46-66 have been added. Thus, claims 46-66 are pending in the instant case.

Restriction

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 46 and 65-66, drawn to a composition of matter comprising a polypeptide or a pharmaceutical composition, related to SEQ ID NO: 8.

II. Claims 46 and 65-66, drawn to a composition of matter comprising polypeptide or a pharmaceutical composition, related to SEQ ID NO: 10.

III. Claim 46, drawn to a composition of matter comprising a nucleotide, vector host cell or a kit related to SEQ ID NO: 7.

IV. Claim 46, drawn to a composition of matter comprising a nucleotide, vector host cell or a kit related to SEQ ID NO: 9.

V. Claim 46, drawn to a non-antibody ligand that binds specifically to the polypeptide related to SEQ ID NO: 8.

VI. Claim 46, drawn to a non-antibody ligand that binds specifically to the polypeptide related to SEQ ID NO: 10.

VII. Claim 46, drawn to an antibody ligand that binds specifically to the polypeptide of Group I.

VIII. Claim 46, drawn to an antibody ligand that binds specifically to the polypeptide of Group II.

IX. Claim 46, drawn to a compound that increase the level of expression or activity of polypeptide of Group I.

X. Claim 46, drawn to a compound that decrease the level of expression or activity of polypeptide of Group I.

XI. Claim 46, drawn to a compound that increase the level of expression or activity of polypeptide of Group II.

XII. Claim 46, drawn to a compound that decrease the level of expression or activity of polypeptide of Group II.

XIII. Claim 46, drawn to a compound that has no effect to the polypeptide according to Group I.

XIV. Claim 46, drawn to a compound that has no effect to the polypeptide according to Group II.

XV. Claim 46, drawn to a vaccine comprising Group I.

XVI. Claim 46, drawn to a vaccine comprising Group II.

XVII. Claim 46, drawn to a vaccine comprising Group.III.

XVIII. Claim 46, drawn to a vaccine comprising Group IV.

XIX. Claim 46, drawn to a transgenic non-human animal to express a polypeptide according to Group I.

XX. Claim 46, drawn to a transgenic non-human animal to express a polypeptide according to Group II.

XXI. Claim 46, drawn to a knockout non-human animal that is absent levels of a polypeptide according to Group I.

XXII. Claim 46, drawn to a knockout non-human animal that is absent levels of a polypeptide according to Group II.

XXIII. Claims 47-64, drawn to a method of using a composition of matter according to Group I.

XXIV. Claims 47-64, drawn to a method of using a composition of matter according to Group II.

XXV. Claims 47-64, drawn to a method of using a composition of matter according to Group III.

XXVI. Claims 47-64, drawn to a method of using a composition of matter according to Group IV.

XXVII. Claims 47-64, drawn to a method of using a composition of matter according to Group V.

XXVIII. Claims 47-64, drawn to a method of using a composition of matter according to Group VI.

XXIX. Claims 47-64, drawn to a method of using a composition of matter according to Group VII.

XXX. Claims 47-64, drawn to a method of using a composition of matter according to Group VIII.

XXXI. Claims 47-64, drawn to a method of using a composition of matter according to Group IX.

XXXII. Claims 47-64, drawn to a method of using a composition of matter according to Group X.

XXXIII. Claims 47-64, drawn to a method of using a composition of matter according to Group XI.

XXXIV. Claims 47-64, drawn to a method of using a composition of matter according to Group XII.

XXXV. Claims 47-64, drawn to a method of using a composition of matter according to Group XIII.

XXXVI. Claims 47-64, drawn to a method of using a composition of matter according to Group XIV.

XXXVII. Claims 47-64, drawn to a method of using a composition of matter according to Group XV.

XXXVIII. Claims 47-64, drawn to a method of using a composition of matter according to Group XVI.

XXXIX. Claims 47-64, drawn to a method of using a composition of matter according to Group XVII.

XL. Claims 47-64, drawn to a method of using a composition of matter according to Group XVIII.

XLI. Claims 47-64, drawn to a method of using a composition of matter according to Group XIX.

XLII. Claims 47-64, drawn to a method of using a composition of matter according to Group XX.

XLIII. Claims 47-64, drawn to a method of using a composition of matter according to Group XXI.

XLIV. Claims 47-64, drawn to a method of using a composition of matter according to Group XXII.

The inventions are distinct, each from the other because of the following reasons:

The inventions listed as Groups I-XLIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions are linked by the technical feature of a polypeptide which is a human placental growth hormone. However this technical feature is not special because it does not constitute an advance over the prior art. Boguszewski Cesar et al (1998, Journal of Clinical Endocrinology and Metabolism, vol. 83, pages 2878-2885 as cited in the IDS) teaches a composition comprising a placental growth hormone (see

Abstract). Because the special technical features of Groups I-XLIV lack novelty or inventive step, and the technical feature of Group I not contributions over the prior art.

Election of Species

3. This application contains claims directed to the following patentably distinct species:

In Group XXIII-XLIV, each method is distinct species in Claim 47 (i.e., diagnosing a disease in a patient; treatment of a disease in a patient; monitoring the therapeutic treatment of a disease; identification of a compound that is effective in the treatment and/or diagnosis of a disease; or screening candidate compounds).

In Group XXIII-XLIV, each method of treatment is distinct species in Claim 49 (i.e., reproductive disorders, pregnancy disorder, such as gestational trophoblastic disease, developmental disorders such as Silver-Russell syndrome, growth disorders, growth hormone deficiency, Cushing's disease, endocrine disorders, cell proliferative disorders, including neoplasm, carcinoma, pituitary tumor, ovary tumor, melanoma, lung, colorectal, breast, pancreas, head and neck, placental site trophoblastic tumor, adenocarcinoma, choriocarcinoma, osteosarcoma and other solid tumors; angiogenesis, myeloproliferative disorders; autoimmune/inflammatory disorders; cardiovascular disorders; neurological disorders, pain; metabolic disorders including diabetes mellitus, osteoporosis, and obesity, cachexia, AIDS, renal disease; lung injury; aging; and infections such as viral infection, bacterial infection, fungal infection or parasitic infection).

These species are related to a polypeptide or nucleic acid according to SEQ ID NO: 7, 8, 9 or 10. However, the related species of compound in claim 64 are distinct because they have distinct structure and/or distinct chemical composition; thus, do not overlap in scope and are not obvious variants. The related species of treatment of disease in Claim 47 is distinct by virtue of distinct symptoms in a patient. The related species of method of treatment is distinct by virtue of distinct patient with distinct symptoms.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution from Claims 46, 47, and/or 49 on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 48, 50-66 are a generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Notice of Possible Rejoinder

1. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election

2. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander D. Kim whose telephone number is (571) 272-5266. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alexander Kim
November 2, 2007

RICHARD HUTSON, PH.D.
PRIMARY EXAMINER